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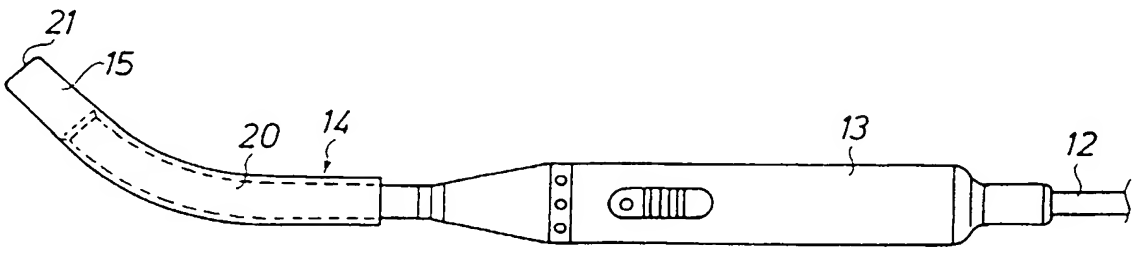
(54) Title: METHOD AND APPARATUS FOR HIGH ENERGETIC ULTRASONIC TISSUE TREATMENT



(57) Abstract: The invention relates to an apparatus for high energetic ultrasonic tissue shrinkage in a target area inside a living body from an outside surface or a body cavity of the living body. The apparatus comprises an ultrasound generator, a device (21) to be applied against the skin or mucous membrane at the site of treatment, and a transducer (28) connected with the ultrasound generator to emit generated therapeutic ultrasound energy through said device. Means are provided for cooling a contact surface of the device (21) to be engaged with the skin or mucous membrane, and the device (21) is made as an exchangeable product forming a heat exchange element between the device and the tissue.

WO 02/056780 A2

Title of the Invention

Method and apparatus for high energetic ultrasonic tissue treatment

Background of the invention

Field of the invention

The invention relates to method and apparatus for high energetic ultrasonic tissue in a target area inside a living body from the outside or a cavity of the living body.

More particularly the invention relates to method and apparatus for eliminating or substantially reducing snoring and opening up or enlarging narrow airways and for tissue shrinkage in the head and neck region by non-invasive ultrasonic medical treatment.

Description of the Prior Art

Snoring is the result of several contributing factors such as narrow airways, enlarged tongue, deviated nasal septum, and enlarged turbinates or nasal polyps. Another reason can be a decrease in upper airway muscle tone, occurring during sleep. These conditions produce an increased airway resistance and a negative intraluminal pressure during inspiration resulting in traction and vibration of tissues in the upper airway. Most prone to vibrate is the soft tissue, including the tonsils, soft palate and uvula but also the tongue base. Snoring is associated with serious health risks. It may result in significant sleep disruption or fragmentation that may lead to daytime fatigue and sleepiness resulting in safety risks. It has been shown that habitual snoring is related to hypertension, hearts

dles electromagnetic energy is delivered which will diminish the tissue by heating.

JP-A-05076538 describes an ultrasonic therapeutic apparatus for treating deceased tissue by heating with ultrasonic energy so as to destroy the deceased tissue, wherein means are provided for detecting the position of the target area and for focusing the ultrasonic energy on that area. A transducer for emitting ultrasound energy from an ultrasound generator is displaceably mounted in a water filled housing partly defined by a membrane which is engaged with the skin or mucous membrane at the treatment site. The position of the transducer is adjusted in relation to the housing and thus in relation to the membrane in order to accurately focus the emitted ultrasound energy on the target area to be treated so that an accurate treatment of the target area will be achieved while avoiding detrimental influence on surrounding tissue as well as skin and mucous membrane.

US-A-4 936 303 discloses a similar apparatus having a housing with a membrane which is engaged with the skin at the treatment site. In this case fluid is circulated through the interior of the housing over the inside surface of the membrane said fluid being temperature controlled to provide a constant surface temperature at the treatment site.

Brief Summary of the Invention

The primary object of the present invention is to provide method and apparatus for high energetic ultrasonic tissue shrinkage in a target area inside a living body from an outside surface or a cavity of the living body in order to achieve a fibrous tissue development and thereby shrinkage of the tissue under mucous membrane or skin in the head

shift and the difference between echoes from positive and negative pulses of either diagnostic or therapeutic ultrasound energy from untreated tissue.

Preferred embodiments of the invention are defined in the dependent claims.

The invention will be described in more detail below with reference to the accompanying drawings showing illustrative embodiments of the invention.

Brief Description of the Drawing

FIG 1 is a side view of a first embodiment of the apparatus of the invention,

FIG 2 is a plan view of an instrument forming part of the apparatus in FIG 1 to be held by the operator the instrument being shown in a straight condition,

FIG 3 is a plan view of the instrument in FIG 2 in a bent condition,

FIG 4 is a partial side view of the instrument in FIGS 2 and 3, which is intended for multiple use,

FIG 5 is a side view of the part of the instrument shown in FIG 4 with an element intended for one way use mounted thereon,

FIG 6 is an end view of the instrument,

FIG 7 is a cross sectional view taken along line A-A in FIG 6,

FIG 8 is a cross sectional view taken along line B-B in FIG 6,

FIG 9 is a cross sectional view taken along line C-C in FIG 6,

FIG 10 is a partial cross sectional view according to FIG 7 showing the instrument in a different adjusted position than that in FIG 7,

FIG 11 is a side view of a second embodiment of the instrument of the invention,

connected to a flange 22. A collar 23 integral with the flange forms an inside annular bead 24 which is snapped over an outside annular bead 25 on a socket 26. Thus, socket 20 with membrane 21 can be separated from bushing 18 in order to be thrown away after use or be sterilized before it is used again. Socket 26 has inside threads 27 engaging the outside threads 19 of bushing 18. Transducer head 15 comprises a piezo-electric crystal 28 forming a concave surface 29 which faces membrane 21 and is connected with two wires 30 which are extended through spring 17 and hose 12 to control unit 10 for the supply of electric current exciting crystal 28. Socket 20 forms two axial passages 31, FIGS 6 and 7, connected to hoses 32 which are extended through hose 12 to control unit 10. A fluid, water or air, can be circulated through passages 31 and the space defined by the concave surface 29 and membrane 21 in order to cool the crystal and the membrane as well as the body surface against which the membrane is applied during operation of the apparatus, but also to expand membrane 21 (see FIG 8) for adjustment of the distance between the crystal and said body in order to focus the ultrasound energy emitted by the crystal, on the target area to be treated in the human body. Adjustment of the distance between the crystal and the body surface is effected by varying the pressure of the circulating fluid. An O-ring 33 seals said space defined by the concave surface 29 and the membrane 21, against the interior of the stem. Optical fibers 34A and 34B are extended through axial passages 35 formed by socket 20, FIGS 6 and 8, and through hose 12 to transmit to the control unit 10 signals representative for the temperature of the membrane 21. Fiber 34A projects light against the back surface of the membrane 21, which can be covered by a temperature sensitive paint that changes color in dependence of the temperature thereof, and the reflected light the color of which is thus dependent of the temperature of

in order to facilitate subsequent signal processing. Output signals from the receiver are transmitted via the converter to an analyzer 105 and to a calculator 106. The analyzer 105 can be an FFT (fast Fourier transform) analyzer or a Doppler analyzer or correlating echoes from negative and positive transmitted ultrasound pulses. A single analyzer of one or a combination of the types mentioned can be provided. The output signal from the analyzer (or each analyzer) is transferred to a complex comparing curcuit here called "a comparator" 107 wherein the signal is compared with a reference earlier stored. The comparator 107 is operatively connected with the transmitter 102. When a comparison indicates that the input signal equals a pre-set reference value the comparator shuts of the transmitter 102. A display 108 is connected to the calculator 106 and the comparator 107.

When the apparatus described is to be used for treatment of a patient the membrane 21 of the instrument 11 is applied against an outside front surface A of the tissue T. By means of diagnostic ultrasound signal pulses generated by the transmitter 101 and transmitted by the crystal 28 via the membrane 21 ultrasound echoes generated by ultrasound energy being reflected at the front and back surfaces A and B, respectively, of the tissue are received by the receiver 103 and are processed in the calculator 106 in order to determine the thickness of the tissue T. The echoes are also transmitted to the comparator 107 via an analyzer 105 of the FFT type for analysis of harmonics in the echo signals or to an analyzer 105 of the Doppler type for analysis of "movements" in the target area, or analysis of echoes from transmitted positive and negative pulses, or to a combination of analyzers of one and the other type, respective, and the output signal(s) from the analyzer(s) is received by the comparator 107.

ing-pulses" positions 3 and 4. Depending on the result the non-invasive treatment is repeated according to the procedure described for 1 to 10 minutes until the desired amount of fibrous tissue in the target area has been developed which is indicated by the comparison made in the comparator. When the signal received by the comparator 107 equals a preset value which indicates that the desired amount of fibrous tissue has been developed by the treatment by means of therapeutic ultrasound, the transmitter 102 is shut off by a signal emitted by the comparator.

A switch 38 is provided on handle 13 of instrument 11 for turning the apparatus on and off, and thus the therapeutic treatment can be interrupted at any time according to the judgement of the operator. Also light emitting diodes 39 are provided on the handle to indicate different phases of the treatment effected by means of the apparatus.

Socket 20 including membrane 21 and flange 22 with collar 23 which during the treatment performed by means of the apparatus come into contact with the patient, should be constructed as an exchangeable unit for either one way use to be discarded after each use, or for sterilization after each use said unit being detached from the instrument at snap attachment 24, 28. The remainder of the instrument which does not contact the patient should be constructed for multiple use.

Referring now to FIGS 11 to 15 in the drawings the instrument 11 disclosed therein comprises a handle 13 provided with switch 38 and indicators 39 and adapted to be connected to the control unit 10 by hose 12. In this case the transducer head 15 is not facing axially from the end of the stem 14 but in the transverse direction thereof. The stem comprises a multiple lumen flexible hose 40 of silicone rubber receiving in a central lumen 41 thereof a metal

ing from the scope of the invention as defined in the claims.

agnostic or therapeutic ultrasound energy from untreated tissue.

7. The apparatus as in claim 6 wherein the comparator (107) is operatively connected with the transmitter (101, 102) to interrupt the transmission of therapeutic ultrasound energy when the echoes of backscattered signals equal a reference signal from untreated tissue.

8. The apparatus as in claim 6 or 7 further comprising a calculator (106) for calculating the thickness of the tissue between two surfaces (A, B) by means of echoes of diagnostic ultrasound energy received at said surfaces.

9. A method for non-invasive ultrasonic wave medical treatment of tissue in a target area inside a living body from an outside surface or a body cavity of the living body comprising the steps of emitting diagnostic and therapeutic ultrasound energy, defining the location of the target area by diagnostic ultrasound energy, concentrating therapeutic ultrasound energy on tissue to be treated medically in the target area, and controlling the condition of the tissue in the target area by backscattered ultrasound between therapeutic ultrasound pulses.

10. The method as in claim 9 wherein the location of the target area is defined by registering echo pulses of diagnostic ultrasound energy emitted against the tissue.

11. The method as in claim 9 or 10 wherein the therapeutic ultrasound energy is focused on the target area.

12. The method as in any of claims 9 to 11 wherein the therapeutic ultrasound energy is pulsed.

13. The method as in any of claims 9 to 12 wherein the therapeutic ultrasound energy is emitted in periods spaced by pauses.

14. The method as in claim 13 wherein the condition of the tissue in the target area is checked by the emission of diagnostic ultrasound energy in said pauses.

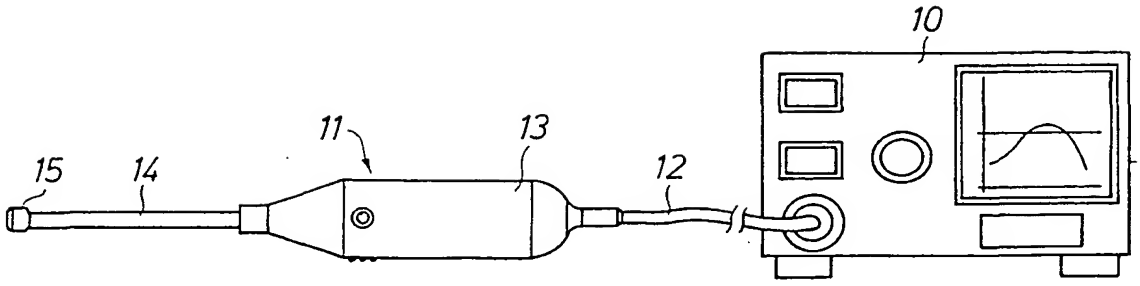


FIG. 1

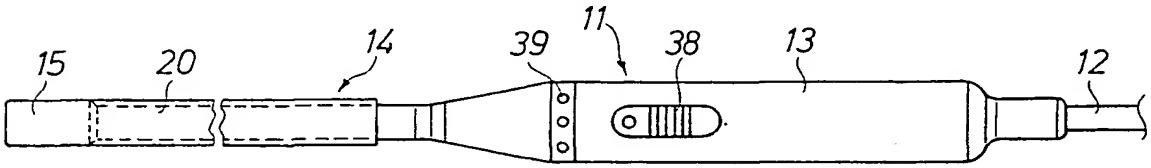


FIG. 2

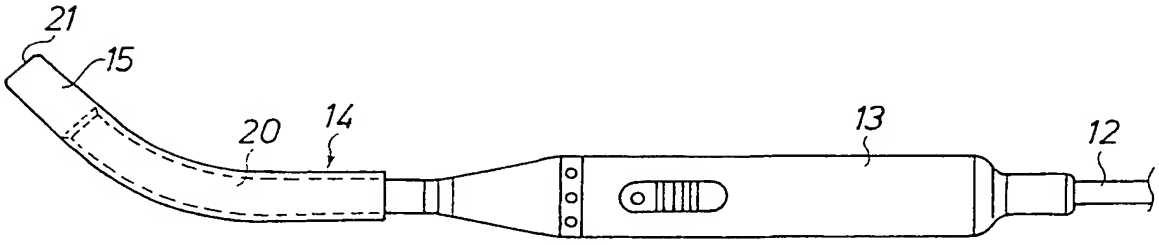


FIG. 3

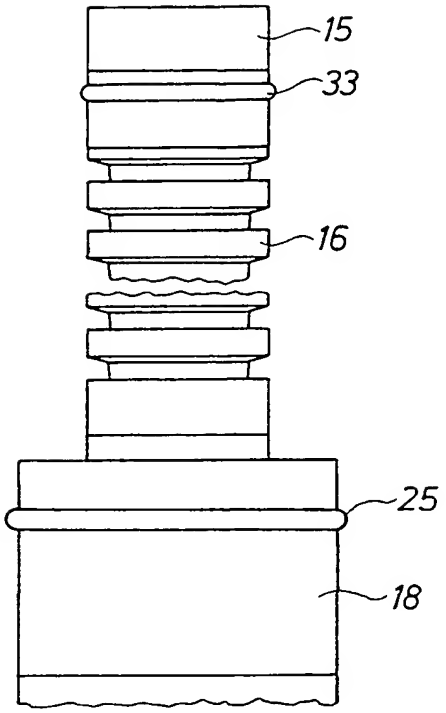


FIG. 4

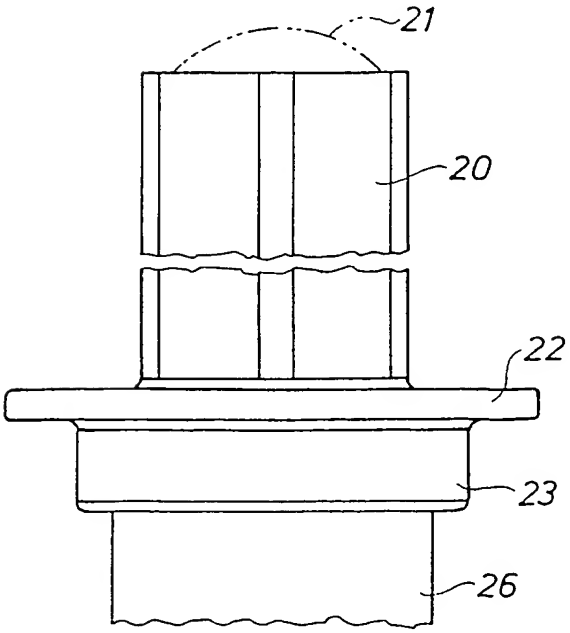
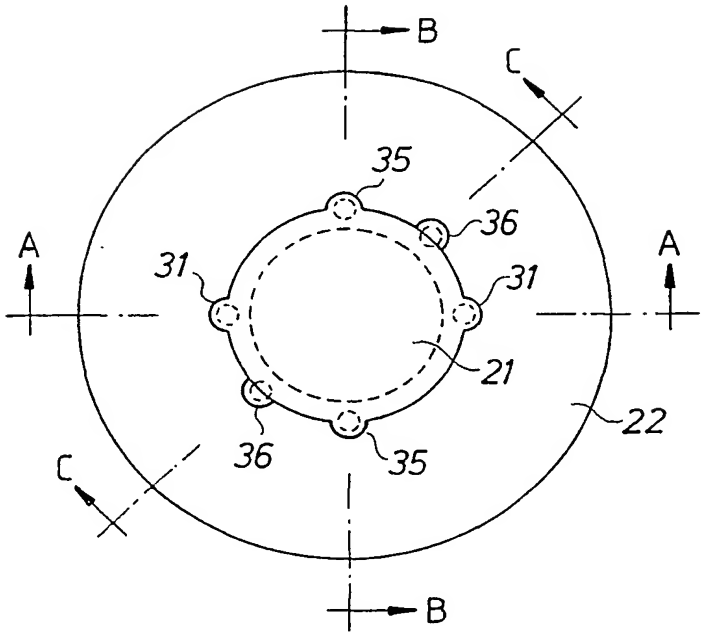


FIG. 5


B
C
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A
A
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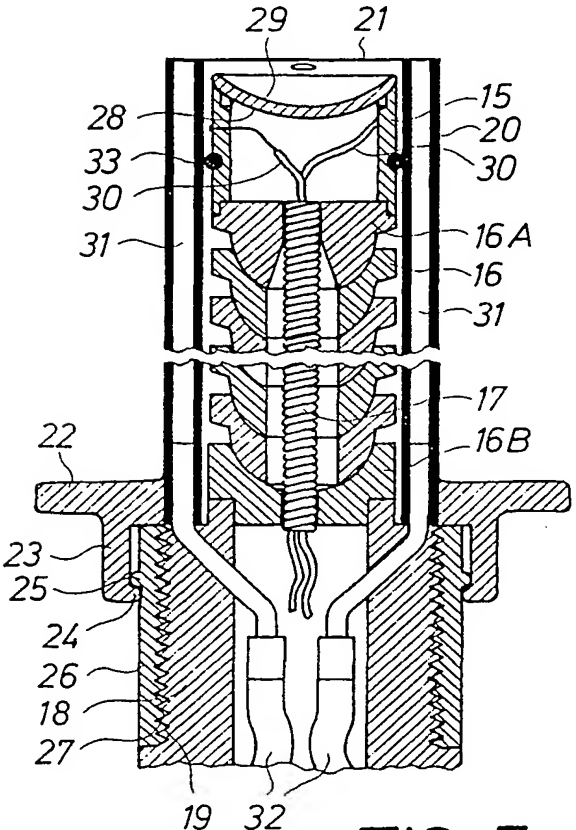
35
C
B

FIG. 6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A-A

FIG. 7

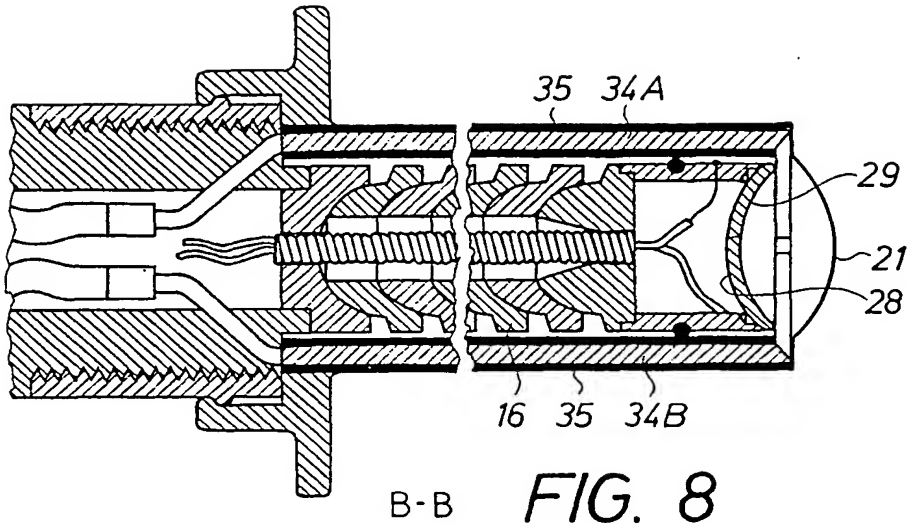

FIG. 8

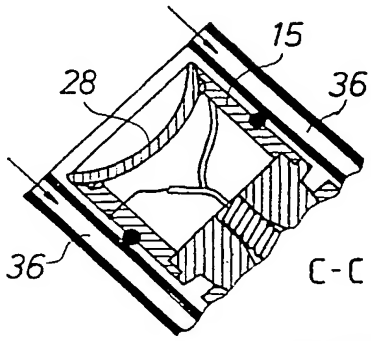

FIG. 9

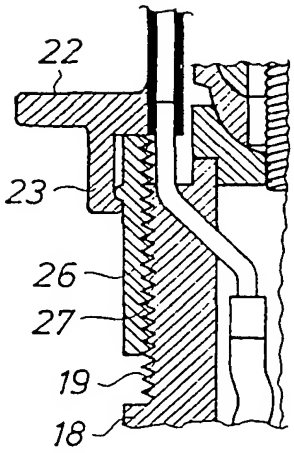

FIG. 10

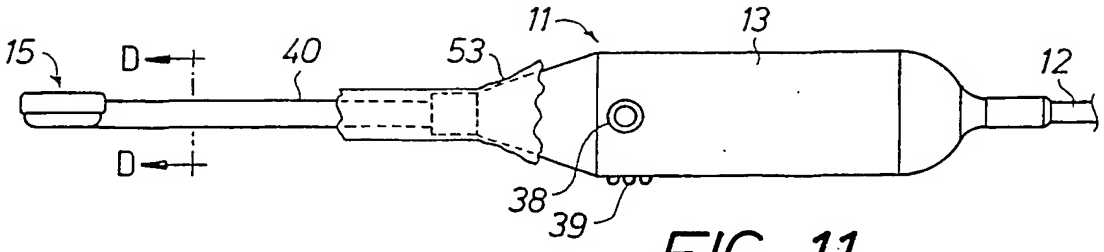

FIG. 11

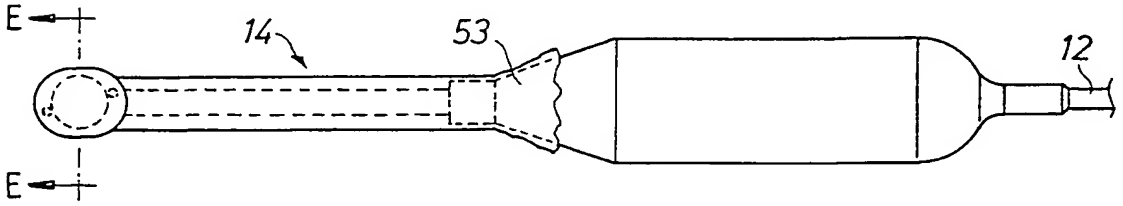

FIG. 12

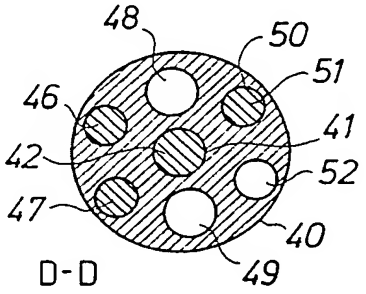

FIG. 13

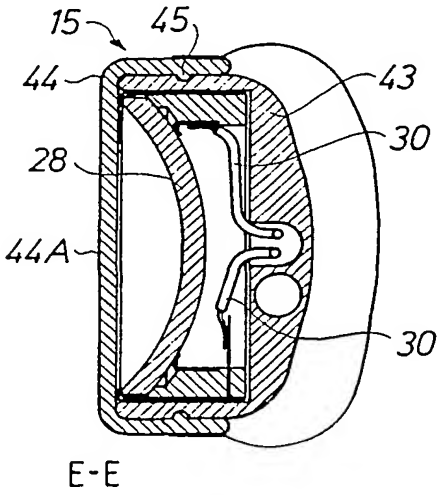

FIG. 14

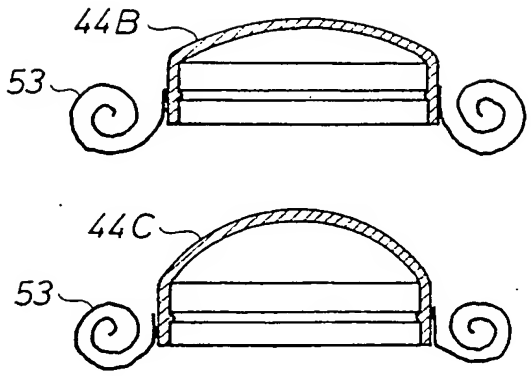

FIG. 15

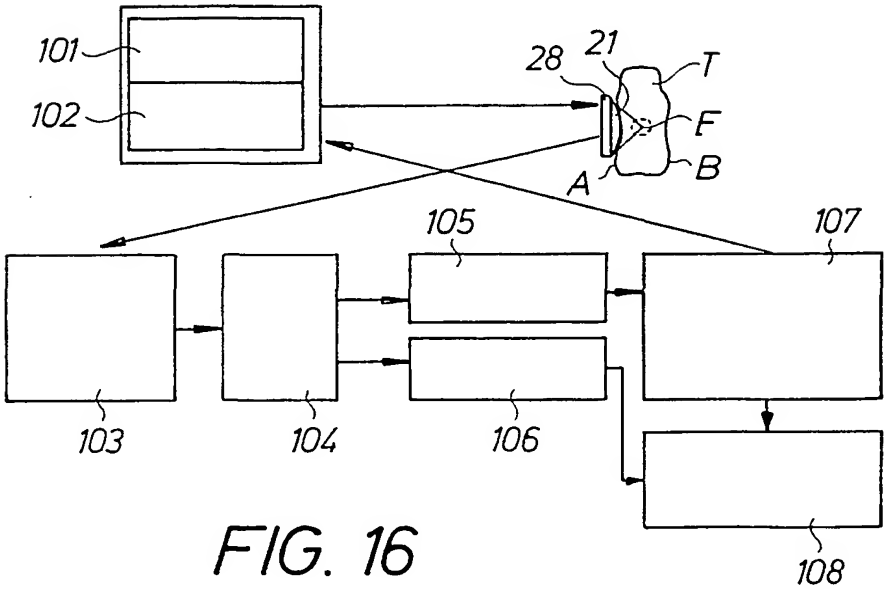

FIG. 16

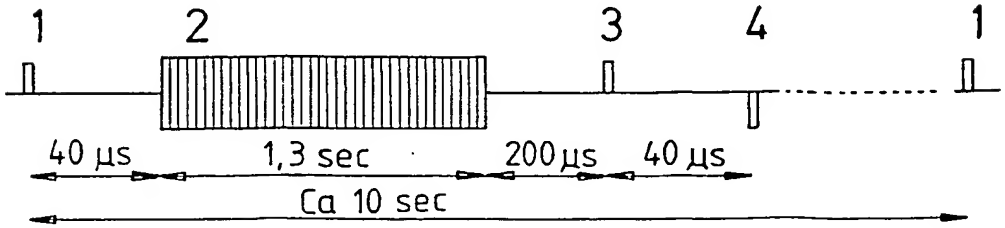

FIG. 17